

REMARKS

Claims 1-3, 5-12, 14-25, and 27-32 remain pending. Claims 5 and 6 were amended to depend from claim 1 as opposed to cancelled claim 4. Claim 10 has been amended to replace "closed" with "curved," which inadvertently was not changed in the previous amendment. Dependent claims 33-36 have been added with claim 33 depending from claim 27, claim 34 depending from claim 33, and claims 35 and 36 depending from claim 10. No new matter is believed to be introduced by way of this amendment.

Regarding claims 35 and 36, Applicant directs Examiner's attention to the Office Action dated August 1, 2006 in which an objection to the drawings was put forth by the Examiner. In the Office Action, it was advanced that,

"The drawings must show every feature of the invention specified in the claims...Figures 1A-8E, do not show a closed ring shaped member must be shown or the feature(s) canceled from the claim(s)."
and,

"A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application."

In Applicant's response dated February 1, 2007, to the August 1, 2006 Office Action, Applicant deleted the term "closed" from claims 10 and 30 "in order to expedite prosecution of the application", however, Applicant expressly reserved the right to later submit a drawing in the application and submit therewith claims including the text "closed ring".

Claims 1-3 and 5-9 have been allowed.

Claims 10-12 and 15-18 were indicated to be allowable if rewritten or amended to overcome the rejection of claims 10-12 and 14-18 under 35 U.S.C. § 112, second paragraph. Independent claim 10 was objected to for lack of antecedent basis for the curved member. Claim 10 has been amended to provide antecedent basis for curved member and claims 10-12 and 14-18 are believed to satisfy all requirements of section 112. In addition to claims 10-12 and 15-18 being allowable, Applicant submits that claim

14 also is allowable because it depends from claim 10 and contains allowable subject matter as well.

Williamson IV 102(b) Rejection:

Claims 19-25, 27, and 29-32 were rejected claims under 35 U.S.C. § 102(b) as being anticipated by Williamson, IV et al. (U.S. Patent No. 6,042,607). Applicant respectfully requests reconsideration and withdrawal of this rejection.

Independent claim 19

Claim 19 recites “a plurality of self-closing clips” and Williamson, IV et al. does not disclose or suggest using self-closing clips. The Williamson, IV et al. staple assemblies 680 include anvils 690, which deform W-shaped staples 720 to close the staples.

The Williamson, IV W-shaped staples include two legs 722 and 724 and a central curved section 736. As a staple is forced in direction 732, legs 722 and 724 move in direction 732 (see e.g., Figures 32 and 34A-D). After a staple center section 736 engages center anvil 690, further movement in direction 732 causes the legs 722 and 724 to fold towards each other until they overlap. (see Figure 32 and col. 22, line 19-col. 23, line 12). The anvils are required to deform and fold the staples because they are not self-closing; they do not close on their own.

Further, Williamson, IV et al.’s assembly 680 does not include a pair of tubes as set forth in claim 29. Claim 19 recites

Heart valve delivery apparatus for placing heart valve prosthesis in a patient’s heart, said apparatus comprising:

a delivery device comprising a plurality of tube pairs arranged to support said heart valve prosthesis; and

a plurality of self-closing clips, each clip having an open configuration and a closed configuration and first and second piercing ends, each clip being ejectably mounted to one of said tube pairs with a first portion of the clip slidably positioned in one tube of the tube pair and a second portion slidably positioned in the other tube of the tube pair so that the first clip piercing end can be ejected from said one tube of the tube pair and said second piercing end can be ejected from said other tube of

the tube pair, each tube having a slot formed therethrough, each slot extending the entire length of a respective tube and configured to allow at least a portion of a respective clip to be ejected therethrough.

Applicants resubmits that Williamson, IV et al.'s assembly 680 does not include a pair of tubes, let alone slots formed therethrough and configured to allow at least a portion of a respective clip to be ejected therethrough as set forth in Applicant's claim 19.

Assembly 680 includes an anvil frame 682, which has a base section 684 having sides 686 and 687, each having an inner surface 688 and 689 to define a cavity CA therebetween (col. 22, lines 26-31). Assembly 680 defines a single cavity having a top opening. Applicant submits that assembly 680 does not define a tube pair, let alone a tube pair as set forth in claim 19.

Independent claim 22

Claim 22 recites:

Heart valve repair apparatus for placing heart valve prosthesis in a patient's heart, said apparatus comprising:

heart valve prosthesis comprising a prosthetic valve leaflet and a member supporting said leaflet; and

delivery apparatus comprising a support for said valve prosthesis and a plurality of clips ejectably mounted to said delivery apparatus support, each clip having two piercing tips extending into said member supporting said leaflet;

further including a plurality of tube pairs, each clip having a first portion slidably positioned in one tube of a tube pair and a second portion slidably positioned in the other tube of said tube pair, each tube having a slot formed therethrough, each slot extending the entire length of a respective tube and configured to allow at least a portion of a respective clip to be ejected therethrough.

The foregoing arguments regarding Williamson, IV's staple assembly not defining the claimed tube pairs also apply to claim 22.

Independent claim 27

Claim 27 recites:

A method for delivering heart valve prosthesis comprising:
providing heart valve prosthesis having a curved member and a skirt extending therefrom and a plurality of self-closing clips, each having two pointed ends, and an open configuration and a closed configuration;
securing the curved member to said plurality of self-closing clips with the two pointed ends of each clip penetrated into the curved member;
placing the curved member on the mitral valve annulus of a patient's heart;
ejecting all of the clips simultaneously to penetrate into the mitral valve annulus and move toward their closed configuration to secure the heart valve prosthesis to the valve annulus.

First, Williamson, IV et al. does not disclose or suggest using self-closing clips. The foregoing comments regarding claim 19 regarding self-closing clips also apply to claim 27.

Further, Williamson, IV does not disclose securing the curved member of a heart valve prosthesis to a plurality of self-closing clips with the two pointed ends of each clip penetrated into the curved member. Williamson, IV et al. discloses stapling a sewing cuff 19 to the annulus of the aorta (see e.g., col. 12, lines 25-27; Figures 12-14). And referring to column 24, lines 22-32, operation of an instrument is described with reference to Figures 39, 40, and 42-25. Figure 42 shows an anchor ring with three rows of staples being shown in a cuff 19. Once the staples are deployed, the heart valve can be moved onto the stapled cuff, and attached thereto. Figures 43-45 show the sequence of attaching a heart valve prosthesis to the anchor ring. Prior to installing the ring, a set of running sutures are connected between the ring and the heart valve. A running suture is one which alternates between the anchor ring and the heart valve prosthesis. Thus, Williamson, IV et al. does not disclose securing a curved member of a heart valve prosthesis to a plurality of staples. Rather, Williamson, IV discloses securing a cuff to an aorta with staples and then securing a heart valve prosthesis to the cuff with other means.

CONCLUSION

Applicant submits that the pending claims are in condition for allowance and respectfully requests the issuance of a formal Notice of Allowance at an early date. If a

telephone interview would advance prosecution of the application, the Examiner is invited to telephone the undersigned at the number provided below.

A request for a two (2) month extension of time under 37 C.F.R. 1.136(a) has been filed with this response. Please charge to Deposit Account No.13-2546 the fee of \$450.00 which is required for the two-month extension of time.

A supplemental information disclosure statement has been filed with this response, please charge any required fees to Deposit Account No.13-2546.

In the unlikely event that the transmittal letter is separated from this document and/or the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due, including additional claims fees, in connection with the filing of this document to Deposit Account No. 13-2546 referencing Attorney Docket No. P-22003.00.

Respectfully submitted,

Date July 24, 2007

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Fidel Realyvasquez, et al.

Examiner: Alvin J. Stewart

Serial No.: 10/814,854

Group Art Unit: 3738

Filing Date: 03-30-2004

Docket No.: P-22003.00

Title: APPARATUS AND METHODS FOR VALVE REPAIR

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application.

Consideration of each of the documents listed on the attached Form 1449 is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicant further requests that a copy of the Form 1449, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

The filing of this supplemental information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Please charge the fee of \$180.00 pursuant to 37 C.F.R. Section 1.17(p) for the submission of this supplemental information disclosure statement to Deposit Account No. 13-2546.

Respectfully submitted,

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